Applicant: Hugh Sharkey and Gary S. Fanton Attorney's Docket No.: 14170-014001 / 25-31-0017

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REMARKS

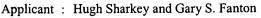
Applicants' remarks are proceeded by the Examiner's comments in small, bold face type.

Claims 48, 50, 74, 75, 77-83, and 85-88 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cosman et al (1984).

Wherein the interior of the electrode is the conductive material and the surface of the electrode is the surface material. Any interstitial fluid present will provide the composite temperature readings referred to. See Figures 2 and 3 and page 946, column 2 to page 948, column 2.

Applicant appears to be arguing that Cosman et al (1984) does not read on the amended claims because there is no disclosure in Cosman et al (1984) to employ the device in an environment as discussed by applicant. This argument must fail for several reasons. Firstly, since the structure taught by Cosman et al (1984) reads on the claimed device, the device of Cosman et al (1984) would inherently behave as applicants claimed structure when put in the same environment. Secondly, the apparatus claims at bar do not recite the environment in which the device is to be used, and in fact cannot properly recite such environment, since this must include the patient's body structures (for example those tissues which would confine any irrigant in the operative space). And thirdly, the device of Cosman et al is intended to be used on the brain and spinal column, which are surrounded by cerebrospinal fluid, which would read on the fluid medium claimed.

Contrary to the Examiner's assertion, Cosman (1984) does not describe or suggest a structure that reads on the claimed device. Cosman (1984) does not describe or suggest a sensor positioned within the thermally conductive material to detect a thermal energy from the selected site and from an adjacent fluid medium, as claimed in independent claims 74, 82, and 89. Cosman (1984) is silent as to the position of the sensor other than specifying that the sensor is built into the small, sharpened tip of the device, and that in use the tip is located in the spinal cord. There is nothing in Cosman (1984) that teaches one skilled in the art to position the sensor in the tip such that the sensor can detect thermal energy from both a selected site and adjacent fluid. Nor does Cosman (1984) describe or suggest that the sensor would detect thermal energy from cerebrospinal fluid, and the Examiner is respectfully requested to provide support for the position that the brain and spinal column "are surrounded by cerebrospinal fluid, which would read on the fluid medium claimed." As such, the Examiner is apparently relying on an inherency argument, i.e., that in use it would be possible to position the tip of Cosman (1984) at a selected



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site such that the sensor of Cosman (1984) would detect thermal energy from the selected site and the adjacent fluid medium. However, such a possibility is not a proper basis for inherency.

To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."... "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Robertson, 169 F.3d 743 (Fed. Cir. 1999).

Cosman (1984) does not describe the subject matter of independent claims 74, 82, and 89 "with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the filed of the invention." <u>ATD Corp. v. Lydall</u>, Inc., 159 F.3d 534.

Furthermore, the position of the sensor is critical to the applicants' invention. If the sensor is not positioned correctly, the sensor will not detect thermal energy from both the selected site and the adjacent fluid medium.

Therefore, claims 74, 82, and 89 and their dependent claims are patentable over Cosman (1984) for at least the reasons discussed above.

Dependent claims 75 and 83 have been amended to recite a surface material separate from the thermally conductive material. Cosman (1984) does not describe or suggest at least this feature of dependent claims 75 and 83.

Claims 74, 76, 82, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosman et al. (1984) in combination with Cosman ('597). Cosman et al. (1984) provide the teachings set forth above. Cosman ('597) teach forming electrodes of stainless steel. It would have been obvious to the artisan of ordinary skill to form the electrode of Cosman et al. (194) of stainless steel since this is a well known electrode material, and useful for forming thermocouple junctions, thus producing a device such as claimed.

Cosman '597 does not overcome the deficiencies in Cosman (1984) discussed above.

Claims 54, 55 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosman et al. (1984) in combination with Makower et al. Cosman et al. (1984) provide the teachings set forth above. Makower et al. teach the equivalence of microwave, radio frequency, and resistive heating in energy delivery devices. It would have been obvious to the artisan of ordinary skill to employ a



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resistive or microwave tissue heater in the device of Cosman et al. (1984), since these are well known equivalents in the art, as thought by Makower et al. and provide no unexpected result, thus producing a device such as claimed.

Makower does not overcome the deficiencies in Cosman (1984) discussed above.

Claims 89-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. in combination with Cosman et al (1984). Makower et al. teach a method such as claimed except for the specific recitation of moving and returning the applicator and the sensor completely enclosed by the thermally conductive material of the probe. Cosman et al (1984) teach a thermistor surrounded by conductive material. It would have been obvious to the artisan of ordinary skill to employ the energy applicator of Cosman et al (1984) in the method of Makower et al, since Makower et al teach no particular form for the high frequency applicator, and to re-insert the probe for subsequent treatment as taught by Makower et al page 20, thus sensing the combined temperature of the tissue and the fluids either exogenous or endogenous, therein, thus producing a method such as claimed.

As discussed above, Cosman (1984) does not describe or suggest the claimed sensor positioned within the thermally conductive material to detect a thermal energy from the selected site and from an adjacent fluid medium. Therefore, claim 89 and its dependent claims are patentable over Cosman (1984) for at least the reasons discussed above.

The absence of an explicit response by the applicant to any of the examiner's positions does not constitute a concession of the examiner's positions. The fact that applicant's comments have focused on particular arguments does not constitute a concession that there are not other good arguments for patentability of the claims.

Applicant's arguments with respect to claims 89-94 have been considered but are moot in view of the new ground(s) of rejection.

Because there are new ground(s) of rejection in the office action, the finality of the office action is not proper. See MPEP § 706.07(b) ("The claims of a new application may be finally rejected in the first Office action in those situations where...all claims of the new application...would have been properly finally rejected on the grounds...of record in the next Office action if they had been entered in the earlier application." Emphasis added.)

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An Information Disclosure Statement was filed in the above-identified patent application on March 23, 1999. Two references submitted in that IDS were neither crossed-out nor initialed when the Examiner returned the Form PTO-1449 which was attached to the Office Action mailed January 31, 2000. Specifically, the Examiner did not indicate that the references of Wilkins et al., "Neurosurgery: Method of Making Nervous System Lesions," ch. 337, pp.2490-2499 and Sluyter, "Radiofrequency Lesions in the Treatment of Cervical Pain Syndromes," Radionics, Inc., 1989, have been considered.

It is therefore again requested that the Examiner consider the references and indicate his consideration on the attached copy of the initialed Form PTO-1449.

Applicant's further request that the Examiner consider and return an initialed copy of the Form PTO-1449 submitted June 27, 2003.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: November 17 2003

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